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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/673,779	01/02/2001	Gijsbert Johan Jansen	80541	4107

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EXAMINER
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CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 03/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/673,779	<b>Applicant(s)</b> JANSEN ET AL.	
	<b>Examiner</b> Suryaprabha Chunduru	<b>Art Unit</b> 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 January 2006.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,5-7,13-15 and 17-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-7,13-15 and 17-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 October 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 3, 2006 has been entered.

***Status of the Application***

2. The action is in response to the RCE filed on January 3, 2006. Currently claims 1-3, 5-7, 13-15, 17-26 are pending. Claim 1 is amended. New claims 23-26. Claims 4, 8-12, 16 are cancelled. All arguments and amendment have been fully considered.

***Specification***

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

(i) The abstract recites the term "said" at several lines. Correction is required.

***Claim objections***

4. Claims 23-26 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 7, 15, 19-20. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing

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one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-713-15, 17-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claim 1 recites “lysis buffer consisting of lysozyme”. The meets and bounds of the claim are unclear and indefinite because recitation of the phrase “consisting of” is unclear, that is, it is not clear how a buffer consists only lysozyme, because buffer means liquid thus the lysis buffer comprises a liquid or water or a solvent as a component in addition to said lysozyme alone. Thus the claims are indefinite for reciting a lysis buffer consisting of.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

A. Claims 1-3, 5-7, 13-14, 17-18, 20,22-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Welling et al. (WO 97/05282) in view of Sheiness et al. (USPN. 5,700,636).

Welling et al. teach a method of claim 1, for identifying the presence of a bacterium in a sample, wherein Nicholas et al. disclose that the method comprises:

(a) testing said sample by Gram-staining on bacterium that indicates Gram-positive bacterium that indicates coccus character (see page 13, line 25-37);

(b) testing said sample with a probe according to an in situ hybridization protocol wherein pre-lysis treatment was performed to identify Gram-positive bacterium (see page 14, line 5-8).

(c) identifying the presence of the bacterium in a sample (see page 13, line 2-36).

With regard to claims 2-3, Welling et al. teach that said sample is clinical sample (see page 7, line 5-21, page 8, line 2-26);

With regard to claims 6, 14, 18, Welling et al. teach that said nucleic acid of microorganism is selected from ribosomal RNA (see page 8, line 20-26);

With regard to claim 7, 23, Welling et al. teach a rRNA probe sequence consisting of SEQ ID. No. 4 as claimed (see page 19, line 32-33);

with regard to claim 20, Welling et al. teach that said hybridization comprises positive and negative controls (see page 12, line 14-27).

With regard to claims 5, 13, 17, Welling et al. teach detection of bacteria comprising Klebsiella pneumonia, Pseudomonas aeruginosa, E.coli (rod-like gram-negative bacteria), Streptococci, Enterococcus (gram-positive chain like coccus) and staphylococcus aureus (gram-positive clumb-like coccus type) (see page 15a-15c, table-1).

With regard to claim 21, Welling et al teach that the method comprises one-step procedure for binding bacteria present in the sample on a microscopic slide (see page 14, line 20-21).

However, Welling et al. did not teach characterizing the presence of bacterium on the basis of the outcome of said Gram-staining.

Sheiness et al. teach a method of claims 1, for detecting microorganism in biological sample, wherein Sheiness et al. also teach use of lysis buffer with lysozyme or proteinase K depending on the type of bacteria to be detected (see col.3, line 49-67, col. 9, line 1-31). Sheiness et al. also teach when the bacteria to be detected is streptococcus type, the lysis buffer comprises lysozyme and proteianse K (see col. 10, line 59-67, col. 11, line 1-5).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to use the method for detecting the presence of bacteria based on gram-stain as taught by Welling et al. with a step of using lysis buffer for characterizing gram-stain of a bacterium as taught by Sheiness et al. for the purpose of developing a sensitive method of detection of a bacterium in a sample. An ordinary practitioner would have been motivated to combine the method of Welling et al. with the inclusion of lysis buffer because Sheiness et al. explicitly taught the differences in lysing gram-negative and gram-positive bacteria and the lysing conditions to release nucleic acids from rigid cell walls of different types of bacteria (see col.9, line 12-31 col. 5, line 17-36) The ordinary artisan would have a reasonable expectation of success to combine the method for detection of bacterium in a sample based on gram-staining as taught by Welling et al. with the characterization of bacteria based on lysis

conditions as taught by Sheiness et al. for the purpose of improving the sensitivity and specificity of the detection of a bacterium in a biological sample.

B. Claims 15, 19, 21, 24-25 rejected under 35 U.S.C. 103(a) as being unpatentable over Welling et al. (WO97/05282) in view of Sheiness et al. (USPN. 5,700,636) as applied to claims 1-3, 5-6, 13-14, 17-18, 20,22 above, and further in view of Hogan et al. (USPN. 5,693,469).

Welling et al. in view of Sheiness et al. teach a method for identifying the presence of a bacterium in a sample as discussed above in section 6A.

Neither Welling et al. nor Sheiness et al. teach probes selected from the group consisting of SEQ ID No. 1 to 3, 5- 12 representing ribosomal RNA sequences.

Hogan et al. teach a method for selecting probe sequences that are complementary to a particular rRNA sequence and computer program to select such probe sequences from know rRNA sequences (that comprise SEQ ID Nos. 1-12 as claimed) to detect microorganisms (see col. 4, line 59-67, col. 5, line 1-61).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine the method of detecting the presence of a bacterium as taught by Welling et al. in view of Sheiness et al. with a step of generate probes for hybridization as taught by Hogan et al. to increase the specificity and sensitivity of the detection method because Hogan et al. explicitly taught a method for selection of probes using a computer program based on known rRNA sequences (see col. 4, line 59-67, col. 5, line 1-61). The ordinary artisan would have had a reasonable expectation of success that such probes generated using known sequences to detect a bacterium present in a sample because the claimed probes (SEQ ID No. 1 to 3, 5- 12) are functional equivalents of the sequences taught by Hogan et al. The ordinary artisan would have been motivated to generate a number of said probes for detection of a bacterium, such

probes are considered functionally equivalent to the claimed probes in the absence of secondary considerations. Further, selection of specific oligonucleotides for specific hybridization conditions represents routine optimization with regard to sequence, length and composition of the oligonucleotide, which routine optimization parameters are explicitly recognized in Hogan et al. As noted in *In re Aller*, 105 USPQ 233 at 235, more particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Routine optimization is not considered inventive and no evidence has been presented that the probe selection performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

**Response to arguments:**

7. With regard to the rejection made in the previous office action under 35 USC 103 (a) over Nicolas et al. in view of Sheiness et al. Applicants' arguments are fully reviewed and considered. And the rejection is withdrawn herein in view of the persuasive arguments and new grounds of rejections.
8. The indicated allowability of claims 7, 15, 19-20 is withdrawn in view of the new rejections as discussed above.

***Conclusion***

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Suryaprabha Chunduru  
Patent Examiner  
Art Unit 1637

*Suryaprabha Chunduru*  
SURYAPRABHA CHUNDURU 3/14/06  
PATENT EXAMINER